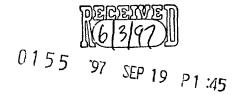




May 20, 1997

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street S.W. Washington, D.C. 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, LEINER HEALTH PRODUCTS notifies the FDA that it has begun using the following phrase and statements:

For Physical and Mental Stress

Ginseng type of herbs have been used globally for centuries by differing cultures as "adaptogens," herbs that help the body safely adapt or react to stressful conditions.

The blend of seven adaptogens in Ginseven, *Powerful Ginseng Complex*, will help build resistance to physical stress, delay muscular fatigue and improve recovery.

Panax Ginseng. Used as a tonic for centuries to help revitalize the body.

Suma Extract. Known as Brazilian Ginseng or "Para Todo" (meaning "for all things"). Used by the Amazonia Indians as a tonic herb.

Notoginseng. Also known as san qi, it is rich in ginsenosides and used for its beneficial effects upon the cardiovascular system.

Siberian Ginseng. Used for 2000 years to help improve mental and physical performance, increasing resistance to stressful conditions.

American Ginseng. Used as a general stimulant, as well as a digestive stimulant.

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Schisandra. This ginseng-like herb is used to improve overall health and improve stamina.

Ashwagandha. Referred to as Indian Ginseng, this "Ayurvedic Herb" (from the world's oldest recorded medical system) has been used to help the body recover after physical exertion.

on the following products:

Your Life® Ginseven

Very truly yours,

LEINER HEALTH PRODUCTS

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs